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REMARKS

1. **Specification Amendments.**

Applicant has amended the specification in order to address the Section 112 issues raised by the Examiner.

2. **Claim Amendments.**

The Claims also have been reviewed and amended to improve syntax of the claims. Further, Claims 1 and 8 have been amended to overcome the Examiner's 35 USC 112 objection. Claims 2 and 3 have been canceled. New Claim 14 has been added.

No new matter has been added any of these amendments.

3. **35 USC 102 Rejection.**

Claims 1-2, 4-5 and 8 have been rejected under 35 USC 102(b) as being anticipated by Friedman et al. (5,160,737). Applicant respectfully traverses this rejection.

In order to properly anticipate Applicant's invention, as claimed, under 35 USC §102, each and every element of the claim in issue must be found, "either expressly or inherently described, in a single prior art reference." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081 (Fed. Cir. 1986); *see also verdegall Bros. V. Union Oil Co. of California,* 814 F2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The absence of one element in the claim in issue from the cited prior reference negates anticipation. *See Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 224 USPQ2d 409 (Fed Cir. 1984). Anticipation was intended to apply in this limited situation in which one prior art reference incorporates ***all*** of the elements of a claim in a subsequent invention because the nonobvious standard was intended to cover broader obvious leaps from a reference to a claim or from combined references to a claim. *See Titanium Metals Corp. v. Brenner*, 227 USPQ 773 (Fed. Cir. 1985).

Friedman requires the use of a release adjusting agent. Friedman also discusses (col. 12, line 54 ff) "sustained release" as being for one hour or longer for plaque prevention or as much as 2-4 weeks or longer for other purposes. Friedman also does not discuss selecting a drug that

is soluble in both water and in alcohol. The combination of the selection of the polymer material and the drug results in the obviation of the need for the release adjusting agent. As water permeates the film the drug is slowly and progressively released.

Claims 8 is rejected under 35 USC 102(e) as being anticipated by Mantelle et al (6,562,363). Mantelle states (col. 4, line 51-54) that the bioadhesive composition is able to maintain direct or intimate contact with the site of application for a number of hours, "up to even 24 hours." Mantelle does not disclose a composition that can maintain effective release of the drug longer than this time period.

Claims 1 and 5 have been rejected under 35 USC 102(b) as being anticipated by Hasegawa et al. (4,701,320). Hasegawa does not teach the combination of components of the present invention and having the extended release time, without the release adjusting reagent.

In summary, none of the cited references anticipate the present invention.

4. 35 USC 103 Rejections.

Claim 3 has been rejected under 35 USC 103(a) as being unpatentable over Friedman et al. (US 5,160,737) in view of Schneider et al. (US 4,980,170). Applicant traverses these rejections.

For a claim to be determined obvious (or nonobvious) under 35 USC 103, the claimed material must have been obvious to person of ordinary skill in the art from the prior art. An obviousness determination requires examining (1) the scope of the prior art, (2) the level of skill in the art, and (3) the differences between the prior art and Applicant's invention. *Litton Systems, Inc. v. Honeywell, Inc.*, 117 SCt 1270 (1970). A mere suggestion to further experiment with disclosed principles would not render obvious an invention based on those principles. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 19 USPQ2d 1432 (Fed. Cir. 1991). In fact, an applicant may use a reference as his basis for further experimentation and to create his invention. *Id.*

The fact that each element in a claimed invention is old or unpatentable does not determine the nonobviousness of the claimed invention as a whole. *See Custom Accessories, Inc., v. Jeffrey-Allan Industries*, 1 USPQ2d 1196 1986 (Fed. Cir. 1986). The prior art must not be given an overly broad reading, but should be read in the context of the patent specifications

and ***as intended by reference authors***. *Durling v. Spectrum Furniture Co.*, 40 USPQ2d 1788 (Fed Cir 1996) (Federal Circuit held that district court erred by giving a "too broad an interpretation" of claims in a sofa patent to invalidate another on the nonobviousness standard).

The Federal Circuit has made it clear that the nonobviousness standard is applied wrongly if a court or an examiner: (1) improperly focuses on "a combination of old elements" rather than the invention as a whole; (2) ignores objective evidence of nonobviousness; (3) pays lip service to the presumption of validity; and (4) fails to make sufficient *Graham* findings. *Custom Accessories, Inc.*, 1 USPQ2d 1196 (Fed. Cir. 1986). Applying the nonobviousness test counter to these principles counters the principle that a patent application is presumed nonobvious. *Id.* To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143.

Friedman has been discussed above. Schneider et al. does not disclose, teach or suggest the combination of the components of the present invention to produce the prolonged effect as shown in the amended claims. The combination of Fridman and Schneider et al. does not render the present invention as claimed obvious.

CONCLUSION

Applicant submits that the patent application is in proper condition for allowance, and respectfully requests such action.

If the Commissioner or the Examiner has any questions that can be resolved over the telephone, please contact the below signed patent attorney of record.

Respectfully submitted,
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